

## REMARKS

Claims 1-48 are pending. Claim 28 has been amended herein to incorporate in part the language of claim 1 from which it depends. Claim 30 has been amended to incorporate in part the language from claim 28, from which it depends. No issue of new matter is believed to be introduced by this amendment. Accordingly, claims 1-48 are currently under consideration.

By this Office Action, the Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

- Group I.      Claims 1-15, 17-21 drawn to an *in-vitro* method of delivering antigen to dendritic cells comprising contacting dendritic cells with apoptotic cells.
- Group II.     Claims 1-16, 18-21, drawn to a method of delivering antigen to dendritic cells comprising contacting dendritic cells with apoptotic cells *in-vivo*.
- Group III.    Claims 22-23, drawn to a method of generating antigen-specific cytotoxic T lymphocytes comprising contacting T lymphocytes with dendritic cells that have been exposed to apoptotic cells expressing an antigen.
- Group IV.     Claim 24, as solely drawn to a method of administering antigen-specific cytotoxic T-cells to an individual with a disease.
- Group V.      Claims 25, 43-45 as solely drawn to a method of administering apoptotic-primed dendritic cells to an individual with a disease for the purpose of activating T-cells.
- Group VI.     Claims 26, 35-42, drawn to an antigen presenting dendritic cell and pharmaceutical compositions thereof.

Group VII. Claim 27, drawn to cytotoxic T lymphocytes.

Group VIII. Claims 28-30, drawn to a method of assessing CTL activity comprising exposing antigen presenting dendritic cells to a population of T cells to be assayed for their ability to exhibit killer cell activity.

Group IX. Claims 31-34, drawn to a method of delivering antigen to dendritic cells comprising contacting dendritic cells with material selected from the group consisting of a reconstituted apoptotic cell system, apoptotic cell fragments, and liposomes comprising at least one antigen and a material which enhances internalization and translocation of antigen to an antigen processing compartment of said dendritic cells.

Group X. Claims 46-47, drawn to a method of activating CD4+ T cells comprising contacting a population of T lymphocytes with dendritic cells which have been contacted with antigen present on necrotic cells.

Group XI. Claim 48, drawn to a method of activating CD4+ and CD8+ T cells against tumor cells comprising a tumor antigen.

Responsive to the Requirement for restriction, Applicants elect to prosecute the invention of Group VIII, claims 28-30, drawn to a method of assessing CTL activity comprising exposing antigen presenting dendritic cells to a population of T cells to be assayed for their ability to exhibit killer cell activity, with traverse.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow

prosecution of more than one group of claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define compositions and methods, with properties so distinct as to warrant separate Examination and Search. Claims 28-30, of Group VIII, as amended, which are drawn to a method of assessing CTL activity comprising exposing antigen presenting dendritic cells to a population of T cells to be assayed for their ability to exhibit killer cell activity are fundamentally related to claims 22-23 of Group III, drawn to a method of generating antigen-specific cytotoxic T lymphocytes comprising contacting T lymphocytes with dendritic cells that have been exposed to apoptotic cells expressing an antigen. In addition, claims 25 and 43-45 of Group V drawn to a method of administering apoptotic-primed dendritic cells to an individual with a disease for the purpose of activating T-cells; and claims 46-47 of Group X, drawn to a method of activating CD4+ T cells comprising contacting a population of T lymphocytes with dendritic cells which have been contacted with antigen present on necrotic cells; and claim 48, of Group XI, drawn to a method of

activating CD4+ and CD8+ T cells against tumor cells comprising a tumor antigen are also fundamentally related to the elected claims of Group VIII. In particular, the claims of these groups are related in the particular steps employed for carrying out the methods. For example, the generation of cytotoxic T cells as covered in claims 22-23 of Group III involve the steps of contacting apoptotic cells with dendritic cells for processing, followed by contacting the dendritic cells with T lymphocyte precursors for a time sufficient to induce activated cytotoxic T cells. Claims 25 and 43-45 of Group V involve methods comprising administration of these apoptotic-cell primed dendritic cells to an individual for the purpose of activating antigen specific T cells. Likewise, claims 46-47 of Group X, and claim 48 of Group XI are drawn to a method of activating T cells by contacting the T cells with dendritic cells which are contacted with an antigen, and the antigen is a tumor antigen (similar to the tumor antigens of claim 29 of the elected group). Applicants assert that the search for any of the methods separately classified by the Examiner as the invention of Group VIII would require an additional search of the identical classes wherein the claims of Groups III, V, X and XI are classified, thus resulting in a duplicate search for the same material. Thus, Applicants submit that the Search and Examination of the entire Application, or, at least, of Groups III, V, X and XI with Group VIII can be made without serious burden, and therefore the Examiner should examine all of the claims of the Application on the merits.

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the claims of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include the claims of Groups III, V, X and XI with the claims of elected Group VIII is in order.

#### *Fees*

No additional fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

*Conclusions*

In view of the above, withdrawal of the Requirement for the Restriction is requested, and an early action on the merits of the claims is courteously solicited.

Respectfully submitted,



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